

REMARKS

By this reply, claims 1-3, 5-13, 15-19, 21-26, 28, 29, 34, 35, 37, and 41 are amended, claims 14, 20, 27, 36, and 40 are cancelled without prejudice or disclaimer, and claims 42-52 are added. Previously dependent claims 5, 6, 9, 21 and 37 have been rewritten into independent form. No new matter has been added. Applicant requests the prompt re-examination and allowance of this application.

Indefinite Rejections

In the Office Action, claims 27, 36, and 40 were rejected under 37 U.S.C. 112, second paragraph, as being allegedly indefinite because they contained the trademark/tradename Eudragit E100. Claims 27, 36, and 40 have been cancelled herein, rendering the rejection thereof moot. Accordingly, Applicant requests that the indefinite rejection be withdrawn.

Anticipation Rejections

In the Office Action mailed August 19, 2009 ("the Office Action"), claims 1, 2, 30, 34, and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,303,144 to Omura ("Omura"), and claims 1, 2, 5-25, 28-32, 34, 35, 37-39, and 42 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,417,682 to Wong et al. ("Wong"). A proper anticipation rejection requires each and every element set forth in the claim to be found in a single prior art reference. MPEP § 2131. Applicant respectfully traverses these rejections because they do not properly establish that each and every claimed element is separately disclosed in Omura or Wong.

Omura discloses a controlled release preparation containing an active ingredient. Omura at col. 4, ll. 30-31, Fig. 1. In the embodiment shown in Fig. 1, the preparation

includes a water insoluble capsule (a female piece) 1A, having one closed end and another open end, a plug (a male piece) 2A fitted into the open end, and a drug 3A sealed in the capsule. Omura at col. 7, ll. 11-15, Fig. 1. In the embodiment shown in Fig. 2, a drug layer 3A and a plug (a male piece) 2A are fitted into a water insoluble tablet outer layer (a female part) 2B. Omura at col. 7, ll. 15-19, Fig. 2.

Wong discloses a device for administering an active agent to a fluid environment. Wong at col. 3, ll. 39-41. In the embodiment shown in Fig. 8, Wong discloses a first wall section 14 and a second wall section 16 (portions 16a, 16b) that are in a slidably telescoping relationship with the first wall section 14 and enclosing an internal compartment 18. Wong at col. 12, ll. 32-35. First wall section 14 includes two opposing open ends and a dividing wall 17. Wong, Fig. 8, *see* Wong at col. 10, ll. 34-36. Wong further discloses that second wall portions 16a, 16b contain expansion means 22a, 22b and moveable partition layers or push plates 24a, 24b between the expansion means 22a, 22b and active agents 30a, 30b. Wong at col. 13, ll. 25-30, Fig. 8; *see* Wong at col. 10, ll. 53-65. As explained in Wong, the movable partition layers or push plates 24a, 24b are impermeable to the passage of fluid and act as means for transmitting a force generated by the expansion means 22a, 22b against the first wall section 14 to separate first and second wall sections 14, 16 (portions 16a, 16b) to release active agents 30a, 30b. *See* Wong at col. 26-30 and 36-38. In operation, the expansion means 22a, 22b absorb fluid, expand and push against push plates 24a, 24b causing them to slide inside compartment 18 and push against first wall section 14 to cause it to slide apart from second wall section 16 (portions 16a 16b). *See* Wong at col. 4, ll. 60-68.

In the Office Action, the plug (male) portion 2A disclosed in Omura and the portion 16b of the second wall section 16 disclosed in Wong were separately characterized as “film” elements. This characterization is in contrast to the recited features in independent claims 1, 5, 6, 9, and 21, as amended herein. Independent claim 1 recites that the first film is “fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening” and independent claim 21 recites that the “second mouth opening . . . is closed by a film fixedly attached to the second mouth opening outside of the second cavity.” Omura instead discloses that the plug (male) portion 2A is disposed within capsule (female) 1A. Additionally, Wong discloses that the second wall section 16 (portions 16a, 16b) telescopically slide relative to the first wall section 14.

Additionally, independent claim 37 includes, *inter alia*, “a first wall extending from [a] base wall in a first direction, and a second wall extending from the base wall in the first direction, wherein the first and second walls define a first cavity having a mouth opening and adapted for connecting a polymer film thereto, and a second cavity having a mouth opening and adapted for connecting a polymer film thereto.” None of the embodiments disclosed in Omura or Wong disclose such an arrangement.

Accordingly, Applicant submits that independent claims 1, 5, 6, 9, 21, and 37 are allowable for at least the respective reasons set forth above. Additionally, dependent claims 2, 7, 8, 10-25, 28-32, 34, 35, 37-39, and 41 are allowable for at least these reasons as well as for their additional features.

Obviousness Rejections

In the Office Action, claims 1, 3, 4, 15, 16, and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wong in view of U.S. Patent No. 4, 281,763 to Pace

("Pace"). A proper *prima facie* case of obviousness requires, *inter alia*, that all claim limitations must be considered when judging the patentability of a claim against the prior art. M.P.E.P. § 2143.03. Applicant respectfully traverses these rejections because all of the claim features of these claims, as amended, have not been considered.

As set forth above Wong fails to disclose each of the features of independent claim 1 and the proposed modification of the disclosure of Wong in view of alleged teachings of Pace that it is known in the art to ultrasonically weld two part drug capsules does not cure the deficiencies noted above with respect to independent claim 1. Accordingly, Applicant submits that claims 1, 3, 4, 15, 16, and 26 are allowable for at least the reasons set forth above as well as for their additional features.

Furthermore, the proposed modification in the Office Action alleges that "[i]t would have been obvious to apply the seal [i.e., a plug and socket sealed via an ultrasonic weld] to the capsule preparation of the '682 patent [Wong] in order to quickly and tightly seal the capsule components." Office Action at pg. 5. The second wall section 16 (portions 16a, 16b) of Wong was characterized in the Office Action, with respect to the anticipation rejection, as the film and the body, respectively. Thus, it appears that the proposed combination of Wong in view of Pace contemplates sealing the second wall section 16 (as characterized as a film) to the first wall section 14, although the obviousness rejection does not necessarily make this clear. Modifying the second wall section 16 to be sealed via an ultrasonic weld to the first wall section 14 would, however, destroy the ability for these wall sections to slide telescopically to release active agents 30a, 30b. Accordingly, such a modification is in contrast to MPEP § 2143.01(V).

New Claims

Claims 42-52 have been added. Applicant submits that these newly added claims are allowable at least because of their claimed features.

Conclusion

In view of the above, Applicant respectfully submits that all of the pending claims are in condition for allowance. Accordingly, Applicant respectfully requests reconsideration and re-examination of this application and timely allowance of this application.

The Office Action contains characterizations of the claims, the specification, and the allegedly related art, with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

If the Examiner believes a telephone conversation might advance prosecution, the Examiner is invited to call Applicant's undersigned representative at 202-408-4397.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By: 

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